

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed October 17, 2008. Claims 1-22 were pending, claims 4 and 11 were withdrawn from consideration, and claims 1-3, 5-10 and 12-22 were rejected in view of cited art.<sup>1</sup> Claims 1-3, 5-10, and 12-22 remain pending.<sup>2</sup>

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

### **B. PRIOR ART REJECTION**

#### **I. REJECTION UNDER 35 U.S.C. § 103**

The Office Action rejected claims 1, 2, 3, 5, 9-10, and 14-22 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,674,231 (*Green*) in view of U.S. Patent No. 6,517,569 (*Mikus*). Claims 7-8 and 12-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Mikus* as applied to claim 1, and further in view of U.S. Patent No. 5,593,412 (*Martinez*). Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over *Green* in view of *Mikus* as applied to claim 1, and further in view of U.S. Patent No. 5,868,755 (*Kammer*). Applicant respectfully traverses.

*Green* was cited as disclosing "the claimed invention except for a skin, or sleeve member, overlying at least a portion of the outer surface between the carrier assembly and a distal end of

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<sup>1</sup> Although the prior art status of the cited art is not being challenged at this time, Applicant reserves the right to challenge the prior art status of the cited art at any appropriate time, should the need arise. Accordingly, any arguments and amendments made herein should not be construed as acquiescing to any prior art status of the cited art.

<sup>2</sup> Support for the claim amendments and/or new claims can be found throughout the specification and drawings as originally filed.

the elongate member and the carrier assembly causing the skin to separate from the outer surface of the elongate member as the carrier assembly is advanced towards the distal end" (Office Action, Page 4). To overcome this deficiency, the Office Action cites *Mikus* for

"a skin or sleeve 20 overlying at least a portion of an outer surface between a carrier assembly 30, 50 and a distal end of the elongate member 15 and the carrier assembly may cause the skin to separate or split from the outer surface of the elongate member from a proximal end of the skin towards a distal end of the skin when the carrier assembly is advanced" (Office Action, Page 4)

Applicant respectfully disagrees with the characterization of *Mikus*. The skin or sleeve 20 identified in the Office Action is disposed within rather than disposed on the outer surface of the elongate member 15 and does not "separate[ or split] from the outer surface of the elongate member." Further, the identified skin or sleeve of *Mikus* does not "separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin as the carrier assembly is advanced towards the distal end," as recited, in part, by independent claim 1. Rather, a distal end of the skin or sleeve separates during proximal movement of the outer sheath 15, and then, following distal displacement of "the distal portion of stent 50 from peel-away sheath 20," "[t]he clinician separates pull handles 24, tearing apart tab 26. The separated halves of peel-away sheath, having been 'peeled-away' from one another, may now be completely retracted from stent 50. Stent 50 does not proximally displace with this retraction because the already-deployed distal end of stent 50 anchors it" (Col. 5, ll. 64-65 and col. 6, ll. 35-41). As such, the skin or sleeve of *Mikus* appears to separate from the distal end first and then from the proximal end toward the distal end following deployment of the stent. As such, *Mikus* neither teaches nor suggests "causing the skin to separate from the outer surface of the elongate member from a proximal end of the skin toward a distal end of the skin as the carrier assembly is advanced towards the distal end" as recited, in part, by independent claim 1.

Similarly, *Mikus* neither teaches nor suggests "advancing the carrier assembly towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be disrupted from a proximal end of the sleeve member toward the distal end of the sleeve member to permit such advancement," as recited, in part, by independent claim 17 or "advancing the carrier assembly towards a distal end of the elongate member, the advancement of the carrier assembly causing the sleeve member to be expanded from a proximal end of the sleeve member toward the distal end of the sleeve member to permit such advancement," as recited, in part, by independent claim 20. Consequently, even if *Mikus* were combined with

*Green*, the combination would still neither teach nor suggest the invention claimed in independent claims 1, 17, and 20.

In addition, even if, *arguendo*, *Mikus* teaches or suggests a skin as proposed by the Office Action, Applicant respectfully submits that there would be no reason to combine the skin or sleeve of *Mikus* with *Green*. "[I]n use, the elongated body 20 of surgical apparatus 10 [*of Green*] is introduced into the interior lumen 102 of blood vessel 104 through a conventional cannula 100 which had previously been extended through the hole 106 formed in the wall of blood vessel 104 during the catheterization procedure" (Col. 7, ll. 18-23). Once positioned, "locator 60 is moved distally . . . from its proximal-most position illustrated in FIG. 13 to its distal-most position illustrated in FIG. 14" (Col. 7, ll. 23-26). "[A]fter the locator 60 is moved into its distal-most position, cannula 100 is withdrawn in a proximal direction" to release the locator arms and expose the clip for deployment (Col. 7, ll. 38-40). As mentioned before in previous office action responses, there would be no reason to modify the teaching of *Green* with the sleeve of *Mikus* because *Green* already includes a sleeve or sheath to protect the delivery device, including the clip. Adding a sleeve or skin would protect a clip that is already protected by the sleeve or sheath. In contrast, the invention of independent claims 1, 17, and 20 includes a sleeve member to protect the clip during distal delivery and deployment.

Further, inclusion of the skin or sleeve in place of the cannula 100 would appear to render the device of *Green* unsatisfactory for its intended purpose. Since the surgical apparatus 10 of *Green* "is introduced into the interior lumen 102 of blood vessel 104 through a conventional cannula 100 which had previously been extended through the hole 106 formed in the wall of blood vessel 104 during the catheterization procedure", there would be a possibility that during the catheterization procedure the skin or sheath would separate or split, thereby being unusable for the catheterization procedure and requiring replacement (Col. 7, ll. 19-23)(emphasis added). In addition, premature separation or splitting would result in the skin or sleeve being unable to maintain the locator arms of the surgical apparatus 10 in a closed configuration before insertion into the blood vessel. Either situation would render the device unsatisfactory for its intended purpose and would also change the principle of operation of the *Green* device.

Turning now to the rejection of claims 7-8 and 12-13 over *Green* in view of *Mikus* and further in view of *Martinez* and the rejection of claim 6 over *Green* in view of *Mikus* and further in view of *Kanner*, Applicant respectfully submits for at least the reasons identified above that neither *Janzen* nor *Mikus*, whether individually or collectively, teaches or suggests the invention

of independent claims 1, 17, and 20. Further, neither *Martinez* nor *Kanner* overcome the *Green* or *Mikus* deficiencies.

Consequently, Applicant respectfully requests withdrawal of the rejection of independent claims 1, 17, and 20, and associated dependent claims 2-3, 5-10, 12-16, 18, 19, 21, and 22, under Section 103 in view of *Green*, *Mikus*, *Martinez*, or *Kanner*, whether collectively or individually.

C. CONCLUSION

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 17th day of March, 2008.

Respectfully submitted,

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